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AdvaMed
Advanced Medical Technology Association

March 5, 2007

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket Number 2006D-0347: Draft Guidance for Industry, Clinical Laboratories, and FDA Staff: In Vitro Diagnostic Multivariate Index Assays

AdvaMed, the Advanced Medical Technology Association, is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatment. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. AdvaMed thanks the FDA for the opportunity to supplement our previous comments made at the FDA February 8, 2007 public meeting on the Draft Guidance on IVDMIAs (see attachment I).

AdvaMed continues to strongly support the goals of the FDA draft IVDMIA guidance that attempts to minimize the confusion regarding the agency's approach toward regulation of certain laboratory-developed tests. However as stated at the February 8 public meeting, many of our members are concerned that all laboratory-developed tests, including IVDMIAs, that are used for clinical diagnostic purposes meet the definition of a medical device and therefore should be subject to the same risk-based regulatory requirements as IVD kits. A few of our members believe IVDMIAs are not a medical device regulated by FDA, but a test system regulated by CMS under the Clinical Laboratory Improvement Amendments of 1988. However, where all members agree is that the IVDMIA guidance is a major change in FDA policy that requires open public dialogue before implementing new regulatory requirements.

After the February 8 meeting, our Diagnostics Task Force met to continue to discuss how best to address the above mentioned concerns. During the AdvaMed meeting, members continued to express their original concerns, but also raised two more specific questions/concerns that can be summarized as follows:

- Considering the amount of confusion that continues to exist among stakeholders in terms of what constitutes an IVDMIA, has FDA obtained adequate public input into the genesis of this new policy?

- How does FDA intend to establish new regulatory requirements with a guidance document that by definition is not binding in nature?

- It is critical for clinical laboratories and IVD manufacturers to have a clear understanding of their regulatory obligations in their "go-to-market" strategies, yet it is still unclear what postmarket regulatory requirements will be applied to IVDMIAs.

As a result, based collectively on all of the above mentioned concerns, if FDA believes IVDMIAs should be regulated as medical devices AdvaMed respectfully recommends that FDA consider the following approach prior to implementation of a final policy:

1. The agency should engage in active dialogue with all stakeholders to vet all concerns and to better understand the consequences of this guidance. We recommend that this can be accomplished by withdrawing the current version or announcing the agency's intent to publish further clarifications contained in the Draft.

2. Simultaneously, FDA should perform an internal legal analysis to determine whether a guidance document is the appropriate mechanism to implement the intent of this policy.

3. While FDA continues to solicit input from all stakeholders, the agency should use its enforcement discretion to allow the continued marketing of existing IVDMIAs that have not demonstrated measurable risk to public health.

AdvaMed thanks FDA for the opportunity to provide this input on the guidance and stands ready to work with FDA and other stakeholders to address these important issues.

Sincerely,

Carolyn D. Jones

Carolyn D. Jones
Associate Vice President
Technology and Regulatory Affairs

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ATTACHMENT I

AdvaMed
Advanced Medical Technology Association

February 8, 2007

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Docket Number 2006D-0347: Draft Statement for FDA Public Meeting In Vitro Diagnostic Multivariate Index Assays

AdvaMed, the Advanced Medical Technology Association is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We want to join the other participants here today in thanking the FDA leadership for holding this public meeting to allow stakeholder input on this important subject.

We support the goal identified in FDA's draft guidance document and applaud your efforts to dispel the confusion that "derives in part from FDA's approach to the regulation of laboratory-developed tests that use . . . FDA–regulated components."

AdvaMed represents a diverse group of interests - from manufacturers of IVDs that are cleared and approved by FDA, companies that make ASRs that are used in laboratory-developed assays, companies that provide laboratory services, and some combinations thereof. The breadth of AdvaMed's membership makes us a good sounding board for diagnostic policies.

The vast majority of AdvaMed IVD membership has concluded that laboratory-developed tests, including an IVDMIA, used for clinical diagnostic purposes meets the definition of a medical device and should be subject to a reasonable risk-based regulatory approach. They believe that laboratory-developed tests should become subject to the same regulatory standard as other IVDs. A few members have concluded that an IVDMIA is not a "medical device" but a test system regulated by CMS under the Clinical Laboratory Improvement

Amendments of 1988 (CLIA). The views of our members almost certainly reflect the discussions taking place among other stakeholders, which is why this public meeting and additional explanation from FDA are important.

All parties agree that patients need timely access to safe and effective new diagnostics. Although the FDA IVD clearance process provides for safe and effective tests, it is still too burdensome and too slow moving for novel technology. It needs further streamlining to meet patient care and public health needs in a timely way.

The FDA IVDMIA guidance document introduces a new FDA policy to actively regulate some "laboratory developed tests" as medical devices – and the clinical laboratories that offer these testing services as medical device "manufacturers". This is a significant change in FDA policy and practice. AdvaMed is here today because the IVDMIA guidance document raises important policy questions that require further clarification, and to raise concerns regarding the process FDA employs to announce new policies.

Because the new IVDMIA policy guidance announces a significant change in policy, we believe the public would be better served by going through a guidance process that allows earlier input so all stakeholders can participate and present their opinions on how such a change in policy will impact public health and the operations of the health care sector most affected – clinical laboratories. The involvement of stakeholders early in the process provides all potentially affected parties (including industry) a better understanding of the purpose of this change, and FDA a better understanding of the potential impact of this new policy. We are glad for the hearing today, but because this guidance raises new policy questions, we believe the process would have been better served if FDA had issued a concept paper and held this meeting **before** issuing the guidance, rather than after.

We believe the guidance as issued, also needs clarification. Because the guidance imposes new requirements, AdvaMed believes that it is important that its scope be clear and unequivocal. For example, based on discussions with stakeholders, it is clear to us that the clinical laboratory community does not understand the types of medical algorithms FDA plans to regulate. They believe the guidance may include medical algorithms that are longstanding tools of medical practice. Therefore, we believe FDA should provide more detailed information regarding which products will be subject to regulation.

In addition, we believe that if FDA goes forward with this initiative as drafted, fairness requires a substantial transition time from the point that FDA publishes any final policy to the date that new policy is enforced. Laboratories will not fully understand which tests are or are not considered an IVDMIA manufacturer by FDA or how to come into compliance with the new regulations unless FDA takes the time to educate these entities and answer their questions.

Finally, we hope and expect that the new FDA thinking and transparency called for in today's meeting will extend to all of our members' enterprises – including those companies

currently regulated by the FDA that are investing heavily in delivering new know-how into worldwide advancements in medicine. To meet the continuing needs of hospitals, physicians, their patients and public health, and to address disease challenges, all constituencies, including our companies, should be invited to work with FDA to develop more streamlined and cost-effective approaches to assure these essential assays are safe and effective for worldwide use.

We will continue to work with FDA and the laboratory organizations to achieve our shared goal of ensuring timely patient access to safe and effective diagnostic tests wherever they are made. Thank you for the opportunity to present here today and we will be offering more extensive recommendations in our submission on this matter before the comment period closes on March 5.

Sincerely,

Carolyn A. Jones

Carolyn Jones
Associate Vice President
Technology and Regulatory Affairs